Turning now to the Office Action, Applicants acknowledge the previous Election of Group I, Claims 1 through 27, 31 and 32, and as the elected species, compounds wherein A is pyridyl group. The Examiner also requires that Applicants further identify a particular species that corresponds to the elected subject matter. However, Applicants respectfully submit that this requirement is improper. Essentially, the basis for issuing an election of species requirement is that the search for all the potential species would be unduly burdensome. Under such circumstances, the Patent Office permits an Election of Species Requirement. However, with respect to the present application, Applicants have already received an action on the merits which addressed all of the elected claims. Therefore, it is not understood why the election of species requirement was issued in this Office Action. However, for completeness, Applicants elect as a particular compound species, for purposes of examination, the compound of Example 48, i.e., N-(2-aminophenyl)-4-[N-(pyrridin-3-yl)methoxycarbonylaminomethyl]benzamide. Continued examination of Claims 1 through 27, 31 and 32 is therefore respectfully requested. Applicants further note that this compound corresponds to the recited generic structure wherein A is a pyridyl group,

X is $-CH_2-$, Q is $-O-\overset{\overset{O}{\|}}{\underset{\underset{H}{|}}{C}}=N$, n = 1, R_1 and R_2 are both H, and R_3 is NH_2.

Based on the foregoing, withdrawal of the election of species requirement is respectfully requested.

Claims 31 and 32 stand rejected under 35 U.S.C. §112, first paragraph, on the basis that the disclosure is only enabling for a method for treating colon cancer. The position of the Examiner is respectfully traversed. As discussed in the subject application, Applicants have made a generic discovery, namely that compounds possessing Formula 1 recited in Claim 1, or pharmaceutically acceptable salts thereof, may be used as pharmaceutical agents, in particular for the treatment of malignant tumors, autoimmune diseases, dermatological diseases, and parasitic disorders. This discovery is based on the fact that the subject compounds exhibit differentiating inducing effect which is therapeutically beneficial in the treatment of such disorders. The anti-tumor activity of the subject compounds find support, e.g., based on the results contained in pages 170 and 177 of the subject application. For example, the pharmacological test of Example 1 provides convincing evidence that the subject compounds increase alkaline phosphatase activity, which is a known indicator for differentiation of cancer cells including human colon cancer cells. Moreover, these results demonstrate that numerous compounds according to the invention exhibited such activity.

Further, Example 2 provides evidence in a mouse tumor model which substantiates that oral administration of compounds according to the invention resulted in enhanced survival in mice having implanted leukemia cells. Specifically, these results were

obtained with mice which were implanted with murine myeloid leukemia cells. Therefore, this provides evidence that the efficacy of the invention is not restricted to colon cancer. Moreover, Example 3 contains results in another mouse tumor model which illustrates that administration of the compound according to the invention resulted in reduced tumor size. Therefore, based on the foregoing, Applicants respectfully submit that there is convincing evidence in the application as to the generic nature of the subject invention. Indeed, no reason or evidence has been provided which would support a conclusion that the subject compounds cannot be used in the treatment of different cancers.

Moreover, with respect to the rejection, Applicants respectfully note that they are claiming a pharmaceutical composition and not a method of treatment. While it is appropriate to give weight to the claim preamble if it is necessary to breathe "life and meaning into the claims", in the present instance it is not. To the contrary, it is quite clear that the claims are directed to any composition suitable for pharmaceutical use, or more particularly for treating tumors, which comprises a pharmaceutically or anti-tumor effective amount of at least one compound according to the invention. Moreover, Applicants have convincingly shown that the subject compounds have anti-tumor activity. Also, this has been demonstrated against different types of tumor cells. Accordingly, withdrawal of the §112, first paragraph, rejection is respectfully requested.

Previous Claims 31 and 32 were rejected under 35 U.S.C. §112, second paragraph, as assertedly being ambiguous. it is anticipated that this rejection will be overcome based on the present amendments. Specifically, Applicants have cancelled Claims 31 and 32 in favor of new Claims 33 through 37. These claims clearly differ from the previous claims in that they are directed to anti-tumor or pharmaceutical compositions which comprise an effective amount of at least one compound according to the invention in combination with a pharmaceutically acceptable carrier. Moreover, some of the claims further provide for specific pharmaceutically acceptable carriers and dosage formulations. The scope of these claims is not identical as an anti-tumor effective amount may be different than for other pharmaceutical applications. Therefore, withdrawal of the §112, second paragraph, rejection is respectfully requested.

Claims 1-27 also stand rejected under 35 U.S.C. §102(a) and (e) as assertedly being anticipated by El-Sayed et al (WO 97/24328). This rejection is made purportedly on the basis that this PCT application claims benefit of prior to a U.S. patent application having a filing date of December 16, 1996. However, the publication date of the PCT document is subsequent to the effective filing date of this application, in particular, the publication date of this reference is October 7, 1997.

Based on the foregoing, Applicants respectfully submit that the §102(a) rejection based on El-Sayed et al is improper. It is improper because the publication date of the reference is after the filing date of this application.

In fact, pending U.S. patent applications are maintained confidential until issuance. Based thereon, even if the rejection were permissible, Applicants would be unable to meaningfully respond to the §102(e) rejection as Applicants are not permitted access to third party pending U.S. patent applications. Based on the foregoing, withdrawal of the §102(a) rejection based on WO 97/24328 is respectfully requested as the October 7, 1997 publication date of this reference is subsequent to the September 26, 1997 filing date of this application.

Claims 1-27 further stand rejected under 35 U.S.C. §102(e) as assertedly being anticipated by El-Sayed et al, WO 97/24328. Withdrawal of this rejection is also respectfully requested as the reference is not available as prior art under §102(e). To the contrary, §102(e)-based rejections are only applicable for issued U.S. patents and, in certain circumstances pending U.S. patent applications, specifically if the pending application has a common Assignee or inventor with the rejected application. However, none of these circumstances is applicable to the facts herein. Accordingly, the §102(e) rejection should be withdrawn as it is improper.

In summary, as the publication date of the El-Sayed et al reference is after the filing date of the subject application, and because this reference is not available as prior art under §102(e), withdrawal of the rejection is respectfully believed to be in order.

Based on the foregoing, this application is believed to be in condition for allowance. A Notice to that effect is respectfully solicited. However, if any issues

remain outstanding after consideration of this Reply, the Examiner is respectfully requested to contact the undersigned so that prosecution may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____

Robin L. Teskin
Registration No. 35,030

P.O. Box 1404
Alexandria, VA 22313-1404
(703) 836-6620

Date: May 11, 1999